

REMARKS

A. Status of the Claims

By the present amendment, claims 1, 5, 22-24, 27, and 39-43 have been amended to more particularly define the Applicants' invention and to claim it with greater specificity. Claims 2-4 and 13 were previously canceled without prejudice, and claims 59-61 have been canceled by the present amendment. Claims amendments and new claims are supported by the original specification and claims. No new matter have been added.

For example, a general structure shown in claim 1 as amended is supported by the matter disclosed in paragraphs [0034]-[0036] on pages 7-8 of the original application, showing the R₃ group attached to the rest of the molecule, and that "R₃ is a phosphate or phosphonate derivative of a therapeutically active agent" is disclosed by the original Figures 1a and 1b as well as in paragraphs [0026], [0051], and [0078] on pages 5, 12, and 22, respectively, of the original application.

Accordingly, the Applicants respectfully request that the amendment be entered. After the present amendment has been entered, claims 1, 5-12 and 14-58 will be pending and will be under consideration.

B. Rejections Under 35 U.S.C. § 112

Claims 1, 5-12, and 14-61 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which allegedly was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention (the written description requirement) (item 4 on page 3 of the Office Action).

Claims 1, 5-12, and 14-61 also stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement (item 6 on page 5 of the Office Action).

Finally, claims 1, 5-12, and 14-61 also stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite (item 9 on page 7 of the Office Action).

Among other reasons for the rejection, the Examiner has stated that the instant specification does not provide enough support that the Applicants were in possession of sulfates, sulfonates, phosphates, lipids, phospholipids, carboxylates, sulfosuccinates, arginine esters, cholesterol esters, carbamates, carbonates, ketals, and the moiety having structure (I). This was used by the Examiner to justify the lack of written description rejection.

The Examiner further stated that the specification only contained a few examples, and there will be required too much experimentation to provide the requisite enablement to all the complexes. In other words, in the Examiner's opinion, claims are too broad (see, page 6, second paragraph of the Office Action). Finally, the indefiniteness rejection seems to have been caused by allegedly imprecise manner in which the structures are presented in the claims.

All the rejections under 35 U.S.C. § 112, both first paragraph and the second paragraph are respectfully traversed.

First, the Applicants respectfully point out that this rejection being raised now amounts to piecemeal examination, which is improper. The matter that triggered the present rejection was present in the original claims and has been before the Examiner from the very beginning of the process of examination. Yet, only now has the Examiner raised these rejections for the first time, having previously objected only to the limitations such as "eye trauma" or "scratching" that allegedly were improper under 35 U.S.C. § 112, first paragraph. It is, however, well established that an Office Action must be

complete as to all matters. The prohibition of piecemeal examination usually applies to rejection of claims, i.e., every valid ground for rejection must be provided in the first Office Action. See, 37 CFR § 1.104 and MPEP § 707.07(g). The Applicants should not be penalized in this situation, and must be entitled at least to an adjustment of a term of any future patent that may issue from the present application.

On the substance of the rejection, while the Applicants respectfully disagree with the Examiner's reasoning, being desirous of accelerating and facilitating the process of examination, the Applicants have amended claim 1. No elements objected to by the Examiner as allegedly having not enough support to demonstrate possession are any longer present in the claims. Thus, the rejection has been rendered moot.

In view of the foregoing, it is respectfully submitted that the rejections under 35 U.S.C. § 112 do not apply. Withdrawal of the rejections and reconsideration are respectfully requested.

C. Rejections Under 35 U.S.C. § 103 (a)

Claims 1, 5-12, 14, 15, 22-52, and 59-61 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Cheng I or Cheng II (see, items 12 and 13 on pages 8-9 of the Office Action). In addition, claims 16-21 and 53-58 stand rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Cheng I or Cheng II in view of U.S. Patent No. 6,120,751 to Unger ("Unger") (item 14 on page 11 of the Office Action). The rejections are respectfully traversed on the following grounds.

As a preliminary matter, the Applicants have noticed that the Examiner thinks that the previously filed arguments have been rendered moot "in view of the new grounds of rejection" (see, item 15 on page 12 of the Office Action). With all due respect, the Applicants fail to see any such "new grounds" and submit that the Examiner is mistaken. The rejection is essentially the same and it would be improper for an examiner not to

consider an applicant's arguments, if a new rejection is not new but is in fact the same as before.

Accordingly, the Applicants respectfully request reconsideration. In view of the new amendments that have been currently made, the Applicants also request the Examiner to consider the following points and to apply the *KSR* standard that has to be satisfied in order to make a valid rejection based on a *prima facie* case of obviousness. This standard was discussed previously.

As regards claim 1, neither Cheng reference discloses or suggests the treatment of particular diseases and disorders recited in claim 1, i.e., of macular degeneration, eye trauma, a pre-existing retinal detachment ocular proliferative or vascular diseases, or diseases of elevated intraocular pressure or inflammation. The Examiner stated that retinitis can be characterized as one of the conditions of eye trauma, thus laying foundation for using Cheng I or II to render claim 1 obvious. The Applicants respectfully disagree with such a conclusion. Retinitis is classically defined as a disease characterized by the inflammation of the retina, e.g., caused by cytomegalovirus infection or by other infection. The term "retinitis" does not include "trauma" which is obviously a reference to a mechanical injury to an eye cause by some kind of blow or impact. Thus, there is nothing in common between these two conditions and it would not be proper to extend the treatments used for retinitis to be used to treat traumas.

The Applicants already previously addressed this point and stated that the teachings of Cheng which are concerned exclusively with the treatments of viral retinitis cannot be extended to the treatment of eye trauma. The Applicants also disagreed with the Examiner on this point and asked him to provide the medical or scientific authority that would support his conclusion that the treatments of retinitis may be used to treat eye injuries. See, the amendment filed January 17, 2008, page 16, last two paragraphs. The Examiner simply ignored this request and just included the same improbable rationale for the rejection. The only difference now that the Examiner previously used the same

grounds to make a lack of novelty rejection and now uses it to make an obviousness rejection.

The Applicants respectfully submit that the Examiner's rationale is equally untenable, whether used to make a lack of novelty rejection or an obviousness rejection. The Applicants respectfully reject the Examiner's notion that retinitis can be characterized as one of the conditions of eye trauma. Such a notion has no support in medical literature anywhere and there is no known treatment of eye traumas using any kind of retinitis medication. The Examiner is respectfully requested to provide evidence to the contrary.

Unger fails to eliminate the above discussed deficiencies of Cheng I or II. Unger only teaches compositions for targeted drug delivery and has not a word discussing or even remotely suggesting any eye treatments. There is nothing in Unger the use of such compositions for the treatment of the above-mentioned ocular diseases and disorders.

It is, therefore, submitted that there is no evidence suggesting a skilled artisan knowing the teachings of Cheng I and II and Unger, would without more, be motivated to make a modification described by the Examiner by combining Cheng I and/or II with Unger. Nor is there anything that would suggest a reasonable expectation of success as a result of such modification. Accordingly, the first two prongs of KSR test have not been satisfied.

In view of the foregoing, it is respectfully submitted claim 1 is patentably distinguishable over Cheng I and II in view of Unger. Each of other claims depends, directly or indirectly, on claim 1, and is allowable for at least the same reason. Reconsideration and withdrawal of the rejection are respectfully requested.

In Re Application Of:
Hostetler et al.
Application No.: 10/770,885
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Attorney Docket No. UCSD1480-1

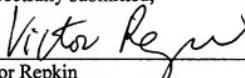
CONCLUSION

In view of the above amendments and remarks, reconsideration and favorable action on all claims are respectfully requested. In the event any matters remain to be resolved, the Examiner is requested to contact the undersigned at the telephone number given below so that a prompt disposition of this application can be achieved.

No fee is deemed necessary with the filing of this response. However, if any fees are due, the Commissioner is hereby authorized to charge any fees, or make any credits, to Deposit Account No. 07-1896 referencing the above-identified attorney docket number.

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Respectfully submitted,


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